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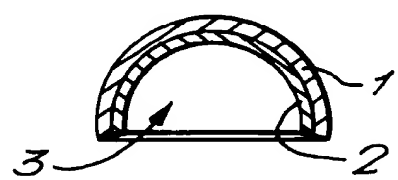
(54) **Prosthetic bearing element and process for making such an element**

(57) A prosthetic bearing element comprising a backing which supports a bearing liner having a bearing surface, said backing being made from a "hard" polymeric material having a minimum hardness value of 55 N/mm^2 and said bearing liner being made from a "soft" elastomeric polyurethane material having a hardness value of 3.0 to 9.0 N/mm^2.

FIG.1.



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Description

This invention relates to a prosthetic bearing element and to a process for making such an element.

At the present time wear of the well known polyethylene acetabular components in hips, the tibial component in knees, and other prosthetic bearing inserts limits the life of these artificial joints. Normally orthopaedic devices for joint construction and reconstruction comprise polyethylene bearings on metal or ceramic or metal on metal for articulation. The polyethylene bearing is often held in a metal shell, for example in hip constructions or a tray in knee constructions. Conveniently bearing liners made from ultra-high molecular weight polyethylene are fixed via a snap fit into the metal backing.

The possible use of elastomers in bearings to provide fluid film lubrication at low velocity, and with a low viscosity lubricant such as in a reconstructed joint has been published in laboratory studies which show that such "soft" bearings provide lower coefficient of friction compared with standard polyethylene versus metal bearings. Such a material is polyurethane.

Because of the fluid film lubrication, it is far less likely that the two bearing surfaces touch during use and thus wear is lower.

It is however difficult to apply this concept for a number of reasons. One difficulty lies in selecting a polyurethane or other elastomer which will not be degraded by the human body so great care must be taken in selecting the polyurethane material used. As mentioned above polyethylene bearing are usually held by physical means in, for example, a metal shell but it is not possible to use this approach with polyurethane because as its stiffness is so much lower than the metal it would be possible for it to extrude from the shell or be easily moved relative to the shell causing damage. Also lower stiffness would lead to greater interface strain.

Because of the above difficulties the Applicants have tried several different approaches. Initially, for ease of use and conventional appearance, it was attempted to bond a polyurethane liner onto a polyethylene backing, similar to pre-existing polyethylene components. This assembly could then be held in a metal shell or cemented depending on the surgeon's preference and clinical judgement.

The present invention therefore is related to a prosthetic bearing element which uses an elastomeric polyurethane bearing material and to a method of manufacturing such a bearing element which overcomes some of the difficulties referred to above.

According to the present invention a prosthetic bearing element comprises a backing which supports a bearing liner having a bearing surface, said backing being made from a "rigid" polymeric material having a minimum hardness value of 65 N/mm^2 and said bearing liner being made from a "soft" elastomeric polyurethane material having a hardness value of 3.0 to 9.0 N/mm^2.

It has been found that bearing elements of this type can be made by a moulding process with the surprising result that when the elastomeric material is applied onto a "rigid" polyurethane backing the stability of the interface appears to be better than that predicted by simple mechanical fit. It is not clear whether there is some form of chemical bond and what precisely causes the excellent adhesion between the two materials. It is possible that an interpenetrating network of the "soft" elastomeric polyurethane into the rigid polymer results.

Preferably therefore the liner is bonded to the backing and the backing itself can also be made from a range of rigid polyurethanes. Suitable polyurethane formulations include those based upon macrogycols formed from polyether glycols i.e. polytetramethylene ether glycol, or polyhexamethylene ether glycol, or polyoctamethylene ether glycol or polydecamethylene ether glycol, or polyester based glycols i.e. poly hexamethylene adipate glycol. The aforementioned macroglycols which are suited to reaction with suitable diisocyanates i.e. 4,4'-methylene bisphenyl diisocyanate, or 4,4'-methylene biscyclohexane diisocyanate, or 2,4-toluene diisocyanate and reacted further with chain extenders i.e. 1,4-butanediol, 1,6-hexanediol, ethylene diamine, 1,4-cyclohexane diamine. Polyurethane of different compositions can be synthesised by those skilled in the art from a range of these materials in many combinations.

A suitable material is Corothane 75D, a rigid segmented linear polyurethane polymer comprising of a polycarbonate based macroglycol, poly(1,6-hexyl 1,2-ethyl carbonate)diol reacted with 4,4'-methylene bisphenyl diisocyanate and chain extended using 1,4-butanediol. The hardness being determined by the ratio of hard segments (formed by the isocyanate and chain extended domains) to the soft segments (formed by the macrogycol portion of the polymer chain) (Corothane is a Registered Trade Mark of Corvita Corporation) or polymethylmethacrylate, or carbon fibre reinforced polybutyleneterphthlate (CFR-PBT). Another alternative material which can be used is carbon fibre reinforced polyetheretherketone (CFR-PEEK).

In a preferred construction the bearing liner is made from Corothane 80A.

A soft segmented linear polyurethane polymer comprising of a polycarbonate based macroglycol, poly(1,6-hexyl 1,2-ethyl carbonate)diol reacted with 4,4'-methylene bisphenyl diisocyanate and chain extended using 1,4-butanediol.

The invention can be applied to an acetabular cup or any other suitable prosthetic bearing.

If desired two or more bearing liners can be provided on the backing thus, the bearing element can be used in this manner in the form of a meniscal or conventional bearing for use in a knee prosthesis.

The invention also includes a prosthetic implant incorporating a bearing element as set forth above.

A process, according to the invention, for making a prosthetic bearing element as set forth above can include a two stage moulding process in which the backing or liner is moulded first and the appropriate liner or backing is moulded onto it.

Thus, the two parts are moulded consecutively rather than simultaneously.

Investigative studies by scanning electron microscopy (SEM), dynamic contact angle (DCA) and fourier transform infra-red spectroscopy (FTIR) have been undertaking to examine the interfacial region to determine the structural changes that occur.

The introduction of barium sulphate ($BaSO_4$) at 5% m/m into the elastomer, Corothane 80A, have shown the interface zone to be discrete at 2 - 5 micron and reproducible. In addition the structural composition of the Corothane 80A and Corothane 75D polyetherurethanes has been examined by recording their spectra over a series of sectors (5µM X 220µM) across a section through the interface region.

This FTIR technique allows the ratio of hard to soft segments in the linear polyetherurethanes to be quantified. The results show that the structure has been modified in the Corothane 75D to gradually change the composition from the interface zone to approximately 50 microns into the bulk as a result of the second moulding operation using Corothane 80A. It is this structural modification that occurs via the overmoulding of the rigid shell materials (Corothane 75D) with the elastomer (Corothane 80A) that appears to provide the adhesion between the two linear polyetherurethanes.

The invention can be performed in various ways and some embodiments together with details of the moulding process will now be described by way of example and with reference to the accompanying drawings in which :

Figure 1 is a cross-sectional view through a typical acetabular cup incorporating the invention;

Figure 2 is a cross-sectional view through a meniscal bearing for use in a knee prosthesis incorporating the invention;

Figure 3 diagrammatically illustrates three stages of moulding a prosthetic bearing element in which the backing is moulded first in a two-part process;

Figure 4 is a diagrammatic illustration showing the stages of moulding a similar bearing element to that shown in Figure 1 moulding the bearing liner first in a two-part process;

Figure 5 is a cross-sectional view through an injection mould for use in the process according to the invention; and,

Figure 6 is a diagrammatic side elevation of an injection moulding machine showing various areas of the injection moulding barrel.

Figure 1 is a cross-section through a prosthetic hip cup according to the invention and which comprises an outer backing 1 which is made from a "rigid" polymeric material having a minimum hardness value of 65 N/mm^2. The backing 1 supports a bearing liner 2 made from a "soft" elastomeric polyurethane material having a hardness value of 3.0 to 9.0 N/mm^2 and a range thickness 1 to 5 mm.

The terms "rigid" and "soft" are used throughout the specification to indicate the relative properties of the material from which the backing and the liner are made.

The bearing surface of the cup shown in Figure 1 is indicated by reference numeral 3.

Figure 2 shows a meniscal bearing surface for use with the tray of a knee prosthesis. The bearing comprises a backing 4 made of a "rigid" polymeric material having a minimum hardness value of $65/Nmm^2$ and an upper liner 5 having a bearing surface 6 and a lower liner 7 having a bearing surface 8. The liners 5 and 7 are made from a "soft" elastomeric polyurethane material having a hardness value of 3.0 to 9.0 N/mm^2 and a range of thickness 1 to 5 mm.

Figure 3 shows diagrammatically a process for moulding a bearing element of the kind shown in Figure 1. The backing 1 is moulded first in a suitable injection mould and which leaves a sprue 9. The backing is now taken out of the mould and the sprue 9 removed. A hole 10 is drilled through the backing 1 which is then replaced in the mould and the liner 2 is moulded by utilising the hole 10. The sprue left by the liner 2 is indicated by reference numeral 11. this is then removed to provide the completed bearing.

Figure 4 shows an alternative way of moulding the bearing element and in this arrangement the liner 2 is moulded first and there is a sprue 12. The liner 2 is taken out of the mould, the sprue 12 removed and the liner replaced in the mould where the backing 1 is moulded onto it. This again produces a sprue which is subsequently removed to provide the finished bearing element.

Figure 5 shows a suitable injection mould which can be used in the process. The general construction of the mould will be familiar to those skilled in the art and will not therefore be described in detail. The mould includes a pair of backing plates 15, 16 which together form a mould cavity 18 which can be fed from an injection moulding machine through an

opening 19.

The mould is in two general parts, 20 and 21, and can be opened along a line 23.

The part of the mould carries a mounting 24 on which can be secured a male moulding element 25. This is secured by a bolt 26.

In order to mould bearing elements of different sizes a number of backing plates 15, 16 and mould elements 25 are provided.

In order to mould in the process shown in Figure 3, that is by moulding the backing element 1 first, a suitably dimensioned moulded element 25 is secured in place together with appropriate backing plates 15 and 16 and the mould press is operated to inject material through the opening 19 into the moulding space 18 to form a backing of the kind shown at the left hand side of figure 3. The mould is now opened along the line 23 and the moulded element 25 together with the backing 1 is detached. The backing, as moulded, is then removed from the mould element 25 and the sprue 9 which has formed in the opening 19 is removed. A hole 10 is now drilled in the backing and the backing is replaced in the mould with a different mould element 25 of smaller dimensions so that there is now a mould opening between the backing 1 and the surface of the mould element 25. Moulding material is now injected through the opening 19 and the hole 10 in the backing 1 so that it fills the space between the backing and the mould element 25. With moulding completed the mould is again split, the moulded bearing element separated from the moulding element 25 and the sprue 11 which has formed in the opening 19 is removed. A hole 10 is now drilled in the backing and the backing is replaced in the mould with a different mould element 25 of smaller dimensions so that there is now a mould opening between the backing 1 and the surface of the mould element 25. Moulding material is now injected through the opening 19 and the hole 10 in thebacking so that it fills the space between the backing and the mould element 25. With moulding completed the mould is again split, the moulded bearing element separated from the moulding element 25 and the sprue 11 which has formed in the opening 19 is removed.

In order to mould according to the process shown in Figure 4 with the same apparatus the process is carried out by using appropriately sized backing plates 15 and 16 and mould element 25 to produce the inner lining. With the sprue 12 removed the lining is replaced in the mould but this time with different backing plates 15, 16 which provide a cavity between the liner 2 and the edges of the cavity 18. The backing is now moulded in place, is removed in a manner described above and the sprue 13 is removed.

It will be appreciated that the above is a relatively simple way of moulding according to the process and other moulding techniques can be employed.

Using the above type of apparatus the following combinations of materials have been moulded using the process set forth and have produced satisfactory examples.

Figure 6 shows a typical commercial injection moulding machine and in which the injection moulding barrel is indicated by reference numeral 30. The various areas along the extending length of the barrel 30 are indicated by reference numerals Z1, Z2, Z3 and Z4. Reference to the temperatures in the barrel are shown in the following examples.

The screw speed and injection speed referred to are dimensionless covering an analogue range from 1.0 to 5.0. They are varied from time to time dependent upon cavity volume or melt viscosity.

1. Moulding CSIR0 85A (lot no 1267-1193)onto Corothane C75D

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (50 bar), Hold (25 bar)	
Cooling mould:	10°C (20 s)	
Screw speed:	3.0	
Injection speed:	4.0	
Injection	temp 205°C	(Z1)
barrel	201°C	(Z2)
barrel	201°C	(Z3)
barrel	191°C	(Z4)

Peel test samples No. 40 to 45 using ptfe tape as crack initiator.

2. Moulding Tecothane 93A onto Corothane C75D

Injection conditions		
Times:	Inj (15 s); Holding (20 s); cooling (20s)	
Pressure:	Injection (050 bar), Hold (25 bar)	
Cooling mould:	10°C	
Screw speed:	3.0	
Injection speed:	4.0	
Injection	temp 205°C	(Z1)
barrel	201°C	(Z2)
barrel	200°C	(Z3)
barrel	191°C	(Z4)

Peel test samples No. 56 to 70 using ptfe tape as crack initiator.

3. Moulding Choroflex AL80A (lot no CF 137) onto Corothane C75D

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (63 bar), Hold (30 bar)	
Cooling mould:	10°C (20 s)	
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 205°C	(Z1)
barrel	201°C	(Z2)
barrel	201°C	(Z3)
barrel	191°C	(Z4)

Peel test samples No. 71 to 87 using ptfe tape as crack indicators.

4. Moulding Pellethane 80A (lot no. 2363) onto Corothane C75D

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (50 bar), Hold (25 bar)	
Cooling mould:	10°C (20 s)	
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 205°C	(Z1)
barrel	201°C	(Z2)
barrel	191°C	(Z3)
barrel	160°C	(Z4)

Peel test samples No. 88 to 102 using ptfe tape as crack indicator.

5. Moulding Corothane 55D (lot no PEA0072) onto Corothane C75D

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (50 bar), Hold (25 bar)	
Cooling mould:	10°C (20 s)	

Continuation of the Table on the next page

(continued)

Injection conditions		
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 222°C	(Z1)
barrel	218°C	(Z2)
barrel	209°C	(Z3)
barrel	190°C	(Z4)

Peel test samples No. 103 to 116 using ptfe tape as crack indicator.

6. Moulding Corothane 80A (lot no PEA00038) onto Tecothane C75D.

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (50 bar), Hold (25 bar)	
Cooling mould:	10°C (20 s)	
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 216°C	(Z1)
barrel	216°C	(Z2)
barrel	205°C	(Z3)
barrel	160°C	(Z4)

Peel test samples No. 117 to 141 using ptfe tape as crack indicator.

Rigid backing pieces were moulded from Corothane 75D as follows.

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (50 bar), Hold (25 bar)	
Cooling mould:	Ambiient (20 s)	
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 229°C	(Z1)
barrel	223°C	(Z2)
barrel	211°C	(Z3)
	200°C	(Z4)

Such backing pieces were ready for use with suitable liners.
Liners themselves were also made individually from Corothane 80A under the following conditions.

Injection conditions		
Times:	Inj (15 s); Holding (20 s)	
Pressure:	Injection (59 bar), Hold (25 bar)	
Cooling mould:	10°C (20 s)	
Screw speed:	3.0	
Injection speed:	5.0	
Injection	temp 208°C	(Z1)
barrel	203°C	(Z2)

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(continued)

Injection conditions		
barrel	191°C	(Z3)
barrel	160°C	(Z4)

These liners were suitable for use with backing of suitable material.

Further "rigid" backing materials can be used for example what are usually referred to as Composites, that is a synthetic resin material with, for example, a fibre reinforcement. Example A set out below was the use of carbon fibre reinforced polybutyleneterphthlate (CFR-PBT).

Times: Inj (4s); Holding (4s)

Pressure: Injection (40 bar), Hold (10 bar)

Temp: Injection 240°C
Mould 80°C

Injection speed: 3

Another alternative material which was successfully injected was polyetheretherketone (CFR-PEEK) as follows.

Times: Inj (4s); Holding (4s)

Pressure: Injection (40 bar), Hold (12 bar)

Temp: Injection 390°C
Mould 180°C

Injection speed: 3

These materials were successfully used as backings, again with, for example, Corothane 80A.

Experiments were carried out to establish the relative hardnesses of different materials and hardness testing of the various elastomers was undertaken using BS 2782; Pt 3 Method 365D (Test load 49N - Shore 80 - 93A; Test load 358N - Shore 75D).

The results of the hardness examination are shown below

Materials	Hardness (Nmm^{-3})
Corothane 80A	5.380 (σ 0.146)
Tecoflex EG93A	4.468 (σ 0.050)
Tecothane TTI080A	5.191 (σ 0.041)
Chronoflex AL80A	3.977 (σ 0.030)
CSIRO 85A	7.894 (σ 0.147)
Corothane 55D	65
Corothane 75D	89.40 (σ 2.31)
Tecothane 75D	84.5 (σ 2.59)

σ denotes standard abbreviation

As will be seen the difference between "rigid" and "soft" are apparent.

A peel test was performed on replicate specimens to assess the bond between the rigid backing and the flexible "soft" layer. the test used is a standard test in which a 3mm thick flexible layer is bonded to an 8mm thick rigid backing with the last 35mm unbonded by masking the interface using PTFE tape. The flexible layer is gripped and pulled at a peel angle of 60° in a Lloyd R6000 Universal testing machine. The force required to peel the layers apart is recorded as the peeling continues for about 50mm.

The table below shows the results of this test where N is the mean peel force, the Strain Energy is the area under the force vs. peel distance curve and the adhesive Fracture Energy is the energy released per unit of new surface created on separating the interface.

Backing shell	Bearing elastomer	Peel force Force (N)	Strain energy (KJm^{-3})	Fracture energy (JM^{-2})
UHMWPE	Corothane 80A	10	n.d.	n.d.
UHMWPE	Tecoflex	1.3	n.d.	n.d.
UHMWPE *pAA	Tecoflex	2.9	n.d.	n.d.
UHMWPE *pHEMA	Tecoflex	2.9	n.d.	n.d.
UHMWPE //NH_3	Corothane 80A	10	0.96	95
UHMWPE //allylamine e	Corothane 80A	4.22	0.15	39.5
Corothane 75D	Corothane 80A	540	6,480	25,700
Tecothane 75D	Corothane 80A	523	9,760	23,520
Corothane 75D	CSIRO 85A	315	n.d.	n.d.
Corothane 75D	Corothane 55D	502	n.d.	n.d.
Corothane 75D	Chronoflex AL80A	403	n.d.	n.d.
Corothane 75D	Pellethane 80A	542	n.d.	n.d.

n.d. denotes not determined

* denotes photochemical grafting

// denotes fuctionalisation of PE by plasma modification

NH_3 (ammonia plasma)

Allylamine (allyamine to quench radicals by an oxygen plasma)

PEI (polyethylenimine to quench radicals generated by an oxygen plasma)

It will be seen that the peel force required for the first six combinations of materials is very low but immediately "rigid" and "soft" materials are applied together the peel force required rises dramatically.

This ability to resist separation is utilised in the preparation of the bearing elements of the kind set forth in the present invention.

Claims

1. A prosthetic bearing element comprising a backing which supports a bearing liner having a bearing surface, said

As will be seen the difference between "rigid" and "soft" are apparent.

A peel test was performed on replicate specimens to assess the bond between the rigid backing and the flexible "soft" layer. the test used is a standard test in which a 3mm thick flexible layer is bonded to an 8mm thick rigid backing with the last 35mm unbonded by masking the interface using PTFE tape. The flexible layer is gripped and pulled at a peel angle of 60° in a Lloyd R6000 Universal testing machine. The force required to peel the layers apart is recorded as the peeling continues for about 50mm.

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Backing shell	Bearing elastomer	Peel force Force (N)	Strain energy (KJm^{-3})	Fracture energy (JM^{-2})
UHMWPE	Corothane 80A	10	n.d.	n.d.
UHMWPE	Tecoflex	1.3	n.d.	n.d.
UHMWPE *pAA	Tecoflex	2.9	n.d.	n.d.
UHMWPE *pHEMA	Tecoflex	2.9	n.d.	n.d.
UHMWPE //NH_3	Corothane 80A	10	0.96	95
UHMWPE //allylamine e	Corothane 80A	4.22	0.15	39.5
Corothane 75D	Corothane 80A	540	6,480	25,700
Tecothane 75D	Corothane 80A	523	9,760	23,520
Corothane 75D	CSIRO 85A	315	n.d.	n.d.
Corothane 75D	Corothane 55D	502	n.d.	n.d.
Corothane 75D	Chronoflex AL80A	403	n.d.	n.d.
Corothane 75D	Pellethane 80A	542	n.d.	n.d.

n.d. denotes not determined

* denotes photochemical grafting

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NH_3 (ammonia plasma)

Allylamine (allyamine to quench radicals by an oxygen plasma)

PEI (polyethylenimine to quench radicals generated by an oxygen plasma)

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Claims

1. A prosthetic bearing element comprising a backing which supports a bearing liner having a bearing surface, said

FIG.1.

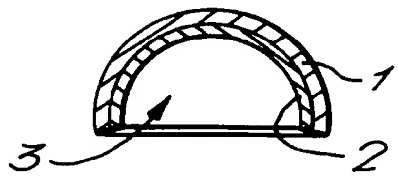
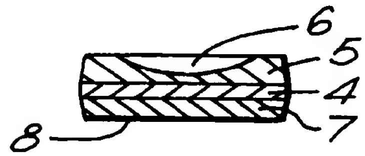


FIG. 2.



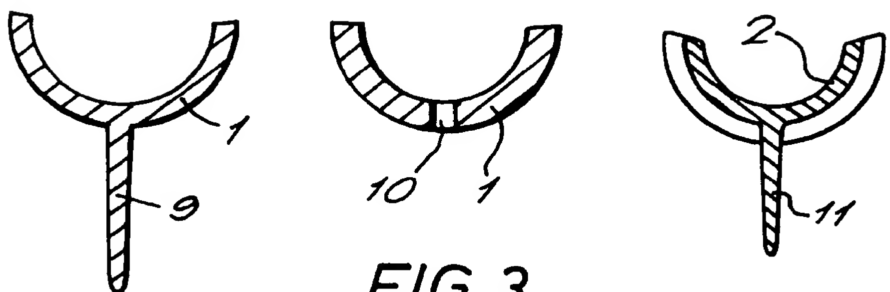


FIG. 3.

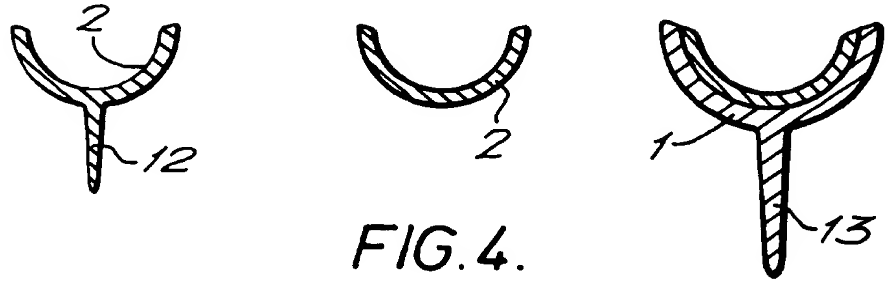


FIG. 4.

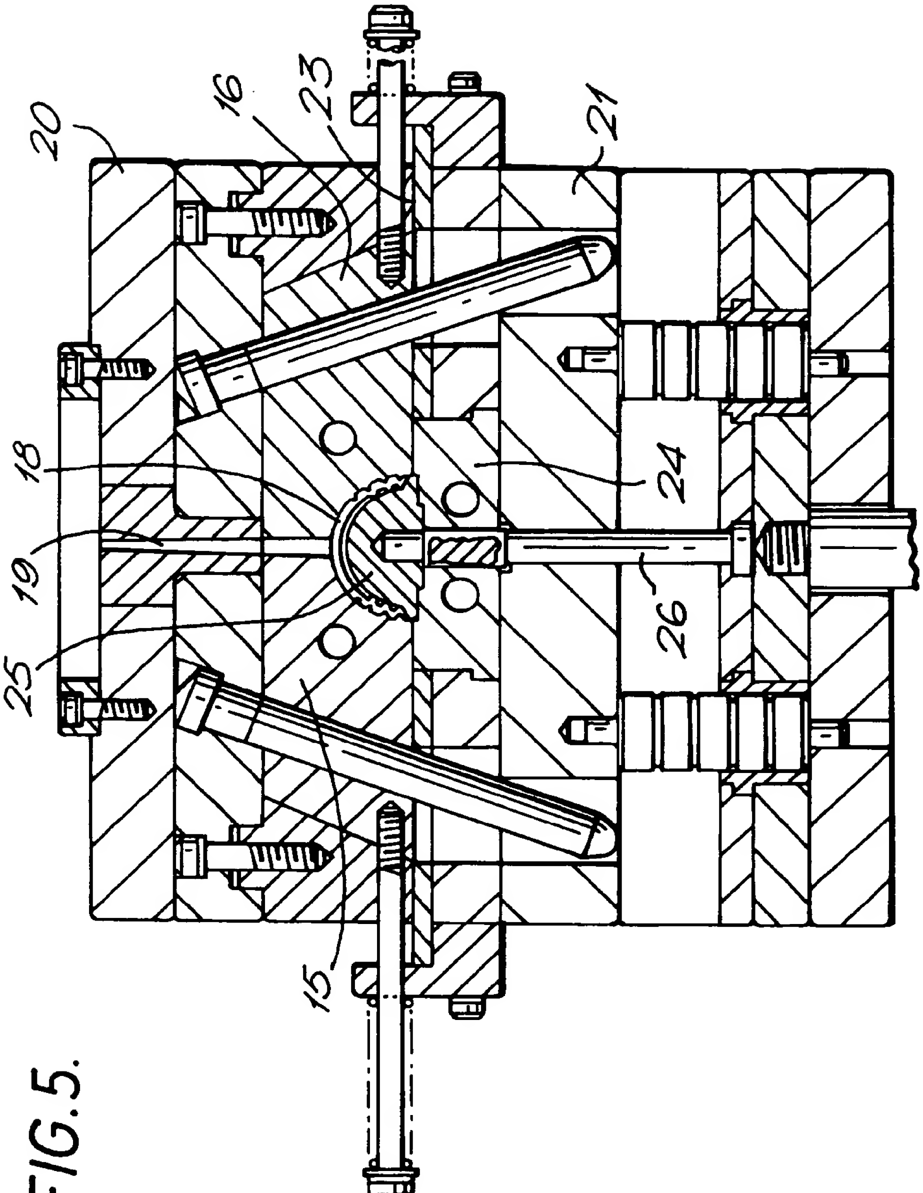


FIG.5.

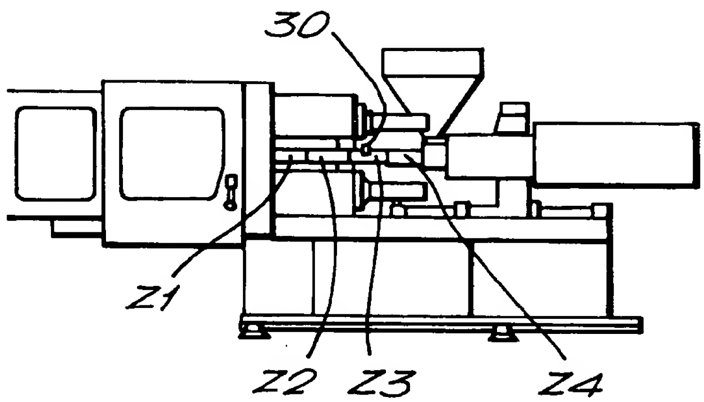


FIG.6.

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